

SANTA BARBARA • SANTA CRUZ

OFFICE OF THE PROVOST AND SENIOR VICE PRESIDENT—
ACADEMIC AFFAIRS

OFFICE OF THE PRESIDENT 1111 Franklin Street Oakland, California 94607-5200 May 3, 2005

Chair Liane M. Randolph Fair Political Practices Commission 428 J Street, Suite 800 Sacramento, CA 95814

Re: Proposed Regulation 18755: Elimination of Completion Statement Requirement on Form 700-U and Exempt Organizations List

Dear Commission Chair Randolph:

Proposed regulation 18755, which is set for hearing before the Fair Political Practices Commission on May 12, 2005, addresses disclosure of financial interests by principal investigators at public universities in California. The University of California submits the following comments concerning the completion statement requirement and the provision concerning exempt organizations.

## A. Completion Statement

Proposed regulation 18755 will require individuals who have principal responsibility for a research project to file initial, interim and completion Statements of Economic Interests on Form 700-U. The University of California requests that the proposed regulation be amended to eliminate the completion statement requirement. The completion statement is not contemplated or required under the statutes or regulations governing financial interest disclosure by researchers. Neither the Political Reform Act nor the Act's implementing regulations in the California Code of Regulations contemplate or require a completion statement.

Proposed regulation 18755 elaborates on the disqualification and disclosure obligations of principal investigators set forth in Regulation 18702.4. Regulation 18702.4, also known as the Academic Decision Regulation, provides that teaching and research decisions made by faculty at an institution of higher learning are not governmental decisions for purposes of the Political Reform Act, and that neither disclosure nor disqualification is required for such decisions.

In 1981 the Commission added a provision to the Academic Decision Regulation, subsection (c)(2), requiring principal investigators to disclose economic interests when a research project is to be funded by a non-governmental entity. That disclosure is made on Form 700-U.

Subsection (c)(2) of the Academic Decision Regulation provides:

"Disclosure shall be required under Government Code section 87302 or any Conflict of Interest Code in connection with a decision made by a person or persons at an institution of higher education with principal responsibility for a research project to undertake such research, if it is to be funded or supported, in whole or in part, by a contract or grant (or other funds earmarked by the donor for a

Chair Liane M. Randolph Fair Political Practices Commission May 2, 2005 Page 2

specific research project or for a specific researcher) from a nongovernmental entity, but disqualification may not be required under Government Code sections 87100, 87302 or any Conflict of Interest Code in

connection with any such decision if the decision is substantively reviewed by an independent committee established within the institution." (Emphasis added.)

Subsection (c)(2) requires disclosure only when the research "is to be funded or supported" by a non-governmental entity and requires independent substantive review only "in connection with a decision ... to undertake ... research."

When a research project ends, there is no funding or support for the research, and there is no decision to undertake research. There is nothing for the principal investigator to disclose, and there is no research decision to be substantively reviewed by an independent committee. For these reasons, the completion statement serves no purpose and contributes not at all to the elimination of bias in research.

The public may be concerned that if the researcher obtains a significant economic interest in the sponsor after a decision to undertake research is made, the integrity of the research may be compromised. This concern is valid, but neither the Political Reform Act nor the Academic Decision Regulation apply. The law is clear — substantive review takes place only in connection with a decision to undertake research and only when the research is to be funded or supported by a non-governmental entity. Completion of the research presents neither of these circumstances.

As to concern that the absence of a completion statement will lead to research bias, the University of California has extensive policies concerning academic and research integrity and takes very seriously the rules and regulations governing ethical conduct of research. The University is subject to extensive federal rules and regulations concerning objectivity in research that reach to all key personnel involved in research studies and to all activities, including the design, conduct and reporting of research. For your background I attach a copy of the University Policy on Integrity in Research which lists other University policies that pertain to integrity in research.

For these reasons, we respectfully request that the completion statement requirement be eliminated for individuals who have principal responsibility for research projects.

## B. Exempt Organizations List

The proposed regulation provides that certain nonprofit organizations that fund research at public universities in California are exempt from the disclosure requirement of the Academic Decision Regulation. The organizations that are currently exempt are listed in the proposed regulation as are the criteria for inclusion on the list.

The University of California has submitted a request to the Commission to add certain nonprofit organizations to the exempt organizations list. The organizations that UC seeks to add are established nonprofit funders of research, such as the American Foundation for AIDS Research, the Christopher Reeve Paralysis Foundation, and the Susan G. Komen Breast Cancer Foundation. We mention this only to note that, if granted, UC's request to add nonprofit organizations to the exempt list will require future modification of the proposed regulation as drafted.

Chair Liane M. Randolph Fair Political Practices Commission May 2, 2005 Page 3

We thank the Commission for taking up these issues and for considering the University of California's comments.

Sincerely,

Lawrence B. Coleman Vice Provost for Research

Enclosure

Cc: Assistant General Counsel Wallace, FPPC University Counsel Jeter, CSU

Cc (w/o enc.):

Executive Director Auriti
Director Schlesinger
Coordinator Landes
Coordinator Smith

## **Research Administration Office**

RECEIVED
FAIR POLITICAL
PRACTICES COMMISSION

## University of California

05 MAY -5 PM 12: 38

Memo Operating Guidance

No. 90-

Supplement #1

June 26, 1990

Subject: University Policy on Integrity in Research

Enclosed is a copy of the University Policy on Integrity in Research and President Gardner's transmittal letter to Chancellors, Laboratory Directors, Senior Vice President--Administration, and Vice President--Agriculture and Natural Resources, dated June 19, 1990, and a copy of the June 22, 1990 cover memoranda to Academic Vice Chancellors from Associate Vice President Moore.

The policy requires Campuses and Laboratories to have necessary guidelines and procedures to provide appropriate responses to allegations of misconduct in research. When extramural funds are involved, local guidelines and procedures also should comply with conditions of the award, including applicable regulations issued. by the sponsor of the research. Copies of local guidelines and procedures shall be sent to the Senior Vice President--Academic Affairs for review as to compliance with the policy.

Associate Vice President Moore offers assistance in the development of local guidelines and procedures and requests that copies of the campus implementation be sent to his office for review.

Refer: Barbara Yoder (415) 642-2886 ATSS 8-852-2886

Subject Index: 01, 02

Organization Index: U-115

David F. Mears

Director

Research Administration Office

Enclosures

Enclosure: C& G Memo 90-1, Supplement

June 22, 1990

ACADEMIC VICE CHANCELLORS

Dear Colleagues:

RE: University Policy on Integrity in Research

Enclosed is the University Policy on Integrity in Research which was recently issued by President Gardner. The Policy reaffirms the University's commitment to integrity in research and calls upon the campuses to ensure that appropriate guidelines and procedures are in place to address allegations of misconduct in research. In addition, the Policy advises campuses of sponsor requirements, such as those required by the National Science Foundation and the Public Health Service, when funds from those agencies are involved.

In the course of the formal review of this Policy, Senior Vice President Frazer transmitted to Chancellors the applicable National Science Foundation and Public Health Service, Department of Human Services regulations as well as the "Framework for Institutional Policies and Procedures to Deal with Fraud and Misconduct in Research" issued by the AAMC and the AAU. These documents are intended to inform the refinement or development of local guidelines and procedures. Should you desire assistance in the development of local guidelines and procedures or need copies of the mentioned documents, my office is available to assist and can provide sample guidelines as well as procedures already developed by some campuses which conform to the new policy.

Finally, as the Policy advises, I would like to request that when your guidelines and procedures are developed they be forwarded to us for review. If you have any questions, please call Director Switkes at (415) 987-9479 or Coordinator Okada at (415) 987-9484. Enclosure Sincerely, Calvin C. Moore Associate Vice President Academic Affairs cc. Senior Vice President Frazer Senior Vice President Brady Chancellors Director Cole **Director Switkes** bcc: Assistant Vice President Levin Acting Deputy Director Gilpin-Bishop Coordinator Lee Coordinator Okada Coordinator Rader

June 19, 1990

**CHANCELLORS** 

LABORATORY DIRECTORS

SENIOR VICE PRESIDENT--ADMINISTRATION

VICE PRESIDENT-AGRICULTURE AND NATURAL RESOURCES

Dear Colleagues:

Enclosed is the University Policy on Integrity in Research. This Policy, which is effective immediately, applies to all employees and students who engage in research activities in the University of California.

The Policy reaffirms the University's commitment to integrity in research and calls for local guidelines and procedures for addressing allegations of misconduct in research. When extramural funds support research activities, local guidelines and procedures should ensure compliance with conditions of the award, including applicable regulations issued by the sponsor of the research. Additionally, local guidelines and procedures also may address issues such as the responsibilities of research supervisors, assignment of credit for publications, training of research apprentices, education on research ethics, requirements for recordkeeping of experimental procedures, and data retention.

The Policy has been developed through extensive review with the campuses, the Laboratories, and the Academic Senate, including the opportunity for employees and employee organizations to comment. Discussions with the Academic Senate should continue at the campus level during the development and implementation of local guidelines and procedures.

Employees and students involved in research should be informed of this Policy and of the applicable regulations of the sponsoring agencies.

Thank you for your advice and cooperation in developing this Policy.

Enclosure

CC:

Members, President's Cabinet Academic Council Chair Spiess Associate Vice President Moore Assistant Vice President Cox Assistant Vice President Levin Director Rogin

Principal Officers of The Regents

University of California

Office of the President

June 19, 1990

UNIVERSITY POLICY ON INTEGRITY IN RESEARCH

**Policy** 

It is longstanding policy of the University of California to encourage and maintain the highest ethical standards in research. This Policy, reaffirms the University's commitment to integrity in research.

Integrity in research includes not just the avoidance of wrongdoing, but also the rigor, carefulness, and accountability that are hallmarks of good scholarship. All persons engaged in research at the University are responsible for adhering to the highest standards of intellectual honesty and integrity in research. Faculty and other supervisors of research activities have a

responsibility to create an environment which encourages those high standards and integrity in research. Open publication and discussion, emphasis on quality of research, appropriate supervision, maintenance of accurate and detailed research procedures and results, and suitable assignment of credit and responsibility for research and publications are essential for fostering intellectual honesty and integrity in research.

University policies set forth expectations for high standards of ethical behavior for faculty and students involved in research and provide procedures for addressing allegations of misconduct in research. Those policies and procedures are set forth in the Bylaws of the Academic Senate, the University Policy on Faculty Code of Conduct and the Administration of Discipline, and University Policies Applying to Campus Activities, Organizations, and Students--Part A, Student Conduct and Discipline. Procedures for administration of discipline also exist for other academic and staff employees in accordance with applicable personnel policies and collective bargaining agreements. (A list of University of California policies which pertain to integrity in research is attached.)

Misconduct means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scholarly and scientific community for proposing, conducting, or reporting research. Misconduct does not include honest error or honest differences in interpretations or Judgments of data./1

The University will continue to take prompt and vigorous action to investigate and address allegations of misconduct in research, based on the following principles:

Institutional and academic responsibility for self-regulation;

Mechanisms to protect to the greatest extent possible the due process rights of the accused, the interests of those making allegations, and the public interest;

The highest degree of confidentiality compatible with an effective response and applicable sponsor reporting requirements; and

Precautions against real or apparent conflict of interest.

Campus and Laboratory Implementation

Campuses and Laboratories shall have necessary guidelines and procedures to provide appropriate responses to allegations of misconduct in research. Such guidelines and procedures should specify how pertinent University policies and procedures will be used to address allegations of misconduct in research by faculty, students, and staff. When extramural funds are involved, local guidelines and procedures also should comply with conditions of the award, including applicable regulations issued by the sponsor of the research. Such regulations include, but are not limited to, the Responsibilities of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science (42 CFR, Part 50, Subpart A) and the National Science Foundation regulations on Misconduct in Science and Engineering Research (45 CFR, Part 689). Among their requirements, these regulations require specific reports to the sponsoring agency.

Chancellors and Laboratory Directors, or their designees, shall be responsible for implementation of this Policy, which may include the consideration of initial reports of misconduct and, when necessary, the referral or initiation of formal investigations. Local guidelines and procedures should clarify available mechanisms for imposing appropriate sanctions or discipline on individuals when the allegation of misconduct has been substantiated. Chancellors and Laboratory Directors, or their designees, shall refer to the University Policy and Procedures for Reporting Improper Governmental Activities and Protection Against Retaliation for Reporting Improper Activities to ensure coordination of allegations of misconduct which may be reported under that Policy and to advise on the procedures to protect against retaliation.

Copies of local guidelines and procedures shall be sent to the Senior Vice President--Academic Affairs for review as to compliance with this Policy.

Note 1/The definition of misconduct is based upon the regulations of the Public Health Service, Department of Health and Human Services (Responsibilities of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science, 42 CFR, Part 50, Subpart A), and it is consistent with the ethical principles and types of unacceptable conduct regarding scholarship listed in the Faculty Code of Conduct and with the types of misconduct specified in the University Policy on Student conduct and Discipline.

University of California Policies which Pertain to Integrity in Research

- 1. University Policy on Faculty Conduct and the Administration of Discipline (June 14, 1974), including the Faculty Code of Conduct (August 26, 1988).
- 2. University Policy on Disclosure of Financial Interest in Private Sponsors of Research (April 26, 1984).
- 3. Policy on Outside Professional Activities of Faculty Members (April 13, 1979).
- 4. Standing Order of The Regents of the University of California 103.1(b), Special Provisions Concerning Officers, Faculty Members, and Employees of the University, Service Obligations.
- 5. University Policy on the Use of Animals in Research and Teaching (October 15, 1984)
- 6. University Policy on the Protection of Human Subjects in Research (September 2, 1981).
- 7. Guidelines on University-Industry Relations (May 17, 1989)
- 8. University Regulation No. 4, Special Services to Individuals and Organizations, Academic Personnel Manual, Section 020, (June 23, 1958).
- 9. University Policies Applying to Campus Activities, Organizations, and Students -- Part A, Student Conduct and Discipline (October 31, 1983).
- 10. Business and Finance Bulletin G-39, Conflict of Interest Policy and Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest (Revised April 15, 1986 and June 15, 1989).
- 11. Guidelines for Disclosure and Review of Principal Investigators' Financial Interest in Private Sponsors of Research (April 27, 1984).
- 12. University of California Patent Policy (November 18, 1985 and revised in part on April 16, 1990).
- 13. University Copyright Policy (August 1,-1975).
- 14. University Policy and Procedures for Reporting Improper Governmental Activities and Protection Against Retaliation for Reporting Improper Activities (January 1, 1990).